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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,853	11/17/2000	Ashvin H. Desai	10284-0269451	8968

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EXAMINER	
ODLAND, KATHRYN P	

ART UNIT	PAPER NUMBER
3743	11

DATE MAILED: 11/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/715,853	DESAI, ASHVIN H.	
	Examin r	Art Unit	
	Kathryn Odland	3743	

-- The MAILING DATE of this communication appears on th cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,9,10,15,17,19-21,24,25,30,33 and 37-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,9,10,15,17,19-21,24,25,30,33 and 37-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated October 8, 2003. Claims 1, 9, 10, 15, 17, 19-21, 24, 25, 30, 33, and 37-41 are pending.

Response to Arguments

1. Applicant's argument regarding a non-invasive imaging technique with respect to claim 1 has been considered but is moot in view of the new ground(s) of rejection. Applicant has amended the claim to require the imaging be "non-invasive." This limitation changes the scope of the claim. Although Edwards et al. does not explicitly recite "non-invasive" imaging techniques, they are extremely well known in the art. Thus, it would be obvious to one with ordinary skill in the art to use "non-invasive" imaging techniques, such as MRI and ultrasound for the purpose of minimizing trauma due to invasion.

2. Applicant's arguments, listed below, filed October 8, 2003, have been fully considered but they are not persuasive.

- Applicant has amended claim 1 to include the term, "viscous" in order to reference the treatment substance. All substances have a component of viscosity and the current application specification does not define viscous relative to any measure. Therefore, the solution of Edwards et al. can be considered viscous. Further, column 16, lines 29-67 discuss the time release falling within the scope of the invention.

- Applicant has also amended claim 1 to include a limitation that the treatment substance is "in the form of a gel or of microspheres, whereby the substance is limited to a localized portion of body tissue." However, column 17, lines 1-5 of Edwards et al. discuss limiting the areas of compound delivery. Also, to reiterate that stated in the previous office action, Edwards et al. clearly disclose microspheres in column 16, lines 29-67. Applicant's attention is drawn to page 3 of the original office action. Although the number (4) was inadvertently not listed in the list of claim numbers, the limitation was clearly addressed in lines 15 and 16 of the original office action and accordingly listed as rejected in the office action summary.
- Applicant has also amended claim 1 to include the limitation "thereby causing selective tissue necrosis in said target tissue." Necrosis is defined as death of cells or tissues through injury or disease, especially in a localized area of the body according to the American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. Edwards et al. disclose chemotherapeutic agents in column 11, lines 7-51. Chemotherapeutic is defined as the treatment of disease using chemical agents or drugs that are selectively toxic to the causative agent of the disease, such as a virus, bacterium, or other microorganism according to The American Heritage® Dictionary of the English Language, Third Edition copyright © 1992 by Houghton Mifflin Company. Therefore, chemotherapeutic agents cause necrosis. Thus, applicant has failed to overcome the previously stated rejection. The rejection is reiterated below.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 9, 10, 15, 17, 19-21, 24, 25, 30, 33, and 38, 39 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. in US Patent No. 5,472,441

Regarding claim 1, Edwards et al. disclose a method for treating a localized portion of body tissue via inserting a needle apparatus in a body, the apparatus including at least one hollow needle core for delivering a viscous treatment substance into the body in the form of a gel or of microspheres, whereby the substance is limited to a localized portion of body tissue, as recited in column 7, lines 45-55, column 8, lines 55-65, column 9, lines 22-25; column 10, lines 1-15, column 13, column 16, column 17, lines 1-5 and column 18, lines 5-13 [wherein the substance of Edwards et al. is considered viscous since the current application does not define viscous relative to any measure]; guiding the needle apparatus to a target tissue in need of treatment, where the guiding includes use of an imaging technique for viewing inside an area of tissue, as recited in column 6, lines 55-65 and column 7, lines 50-55; applying the treatment substance to the target tissue through the needle apparatus, wherein the treatment substance includes a component selected from the group of tissue necrosis agents, as recited in column 8, line 57 and column 11, lines 5-52 [where chemotherapeutic agents cause necrosis],

thereby causing selective tissue necrosis in the target cell, as recited in column 9, lines 20-25 and column 11, line 61. However, Edwards et al. do not explicitly recite a non-invasive imaging technique. On the other hand, non-invasive imaging techniques such as MRI, ultrasound, etc. are extremely well known in the art. Thus, it would be obvious to one with ordinary skill in the art to use a non-invasive imaging technique for the purpose of reducing trauma due to invasion.

Regarding claim 9, Edwards et al. as modified disclose that as applied to claim 1 as well as applying RF energy to the target tissue through an RF electrode, as recited in column 9, lines 60-65.

Regarding claim 10, Edwards et al. as modified disclose that as applied to claim 9 as well as a substance that includes an electrically conductive component; as recited in column 16, line 16.

Regarding claim 15, Edwards et al. as modified disclose that as applied to claim 1 as well as a substance with an imaging contrasting agent, as recited in column 17, lines 1-4.

Regarding claim 17, Edwards et al. as modified disclose that as applied to claim 1 as well as microspheres that include an imaging contrasting agent, as stated in column 17, lines 1-3.

Regarding claim 20, Edwards et al. as modified disclose that as applied to claim 1 as well as microspheres the include a container holding therein a gas and a substance selected from the group consisting of a gel and a liquid for providing image enhancement when the imaging technique is ultrasound, as recited in column 16 and column 17, lines 1-5. Given the claim does limit the imaging to ultrasound, when ultrasound is used the liquid would provide image enhancement.

Regarding claim 21, Edwards et al. as modified disclose that as applied to claim 1 as well as a target tissue that is in a prostate and wherein the method is for treating a condition selected from the group of BPH and prostate cancer and is accomplished by a method selected from the group of Transrectal, Transurethral and Transperineal approach, as recited in column 6, lines 60-63 and 08/148,441 which is incorporated by reference in column 1, line 11 (a copy has been provided).

Regarding claim 24, Edwards et al. as modified disclose that as applied to claim 1 as well as the method applied for treatment of a body part selected from the group of prostate, liver, uterus, bladder, kidney, lung and breast; as recited in column 4, line 14.

Regarding claim 25 Edwards et al. as modified disclose that as applied to claim 24 as well as inserting that is accomplished using an approach selected form the group of percutaneous, laparoscopic, and endoscopic, as recited in column 6, lines 55-65.

Regarding claim 30, Edwards et al. as modified disclose that as applied to claim 1 as well as guiding that is further performed using a device selected from the group of biopsy apparatus, laparoscope, endoscope, hysteroscope, MRI, CT scan, and ultrasound imaging apparatus, as recited in column 6, lines 55-65.

Regarding claim 33, Edwards et al. as modified disclose that as applied to claim 1 as well as inserting that is performed by at least one method selected from the group of percutaneous, through incision, and through a natural body opening, and a laparoscopic approach, as stated throughout.

Regarding claim 38, Edwards et al. as modified disclose that as applied to claim 1 as well as microspheres that have a gas (some air inclusion is inherent).

Regarding claim 39, Edwards et al. as modified disclose that as applied to claim 38 as well as a gas that is selected form the group of *air*, helium, fluorocarbon, and carbon dioxide.

Regarding claim 41, Edwards et al. as modified disclose that as applied to claim 10 as well as a conductive component that is selected from the group consisting of conductive polymers, conductive agents, conductive elements, conductive particles and metallic suspensions, as recited in column 16, line 16.

5. Claims 37 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards et al. in US Patent No. 5,472,441 in view of Barker et al. in JP 405078237.

Edwards et al. as modified disclose that as applied to claim 1 as stated above. However, Edwards et al. do not explicitly recite a treatment substance that is in the form of a gel and a gel wherein the gel further has a binding agent and that binding agent is selected form the group of biomaterial, polymer, biodegradable polymer, a suspension agent, a derivative of a protein, fat, collagen and oil. On the other hand, Barker et al. teach a treatment substance that is in the form of a gel and a gel wherein the gel further has a binding agent and that binding agent is selected form the group of biomaterial, polymer, biodegradable polymer, a suspension agent, a derivative of a protein, fat, collagen and oil, as stated in the purpose and constitution. Therefore, it would be obvious to one with ordinary skill in the art at the time the invention was made to modify the invention of Edwards et al. to use a gel for the purpose of increasing viscosity allowing more controlled delivery.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1, 9, 10, 15, 17, 19-21, 24, 25, 30, 33, and 37-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,231,591 in view of Unger et al. in US Patent No. 5,542,935.

Although the conflicting claims are not identical, the claims of the current application are broader in some respects and more specific in others. The claims of U.S. Patent No. 6,461,296 do not recite a treatment that is a microsphere. On the other hand, Unger et al. teach of therapeutic drug delivery via microspheres, as stated in the abstract. Therefore, it would also be obvious to incorporate microspheres for the purpose of timed/controlled release.

Further, there is recitation of non-invasive imaging and necrosis.

6. Claims 37 and 41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 9, 20, 21 and 23 of U.S. Patent No. 10/274,436. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter, perhaps slightly broader in some aspects while a slightly more narrow in others.

7. Claims 1, 9, 10, 15, 17, 19-21, 24, 25, 30, 33, and 37-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 10/ 300,655.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter, perhaps slightly broader in some aspects while a slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 1, 9, 10, 15, 17, 19-21, 24, 25, 30, 33, and 37-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-46 of copending Application No. 10/ 265,209. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are merely reworded representations for the same subject matter, perhaps slightly broader in some aspects while a slightly more narrow in others.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KO

Henry Bennett
Supervisory Patent Examiner
Group 3700